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Assessment of Laboratory Quality Management System (QMS) in the Republic of Tajikistan

March 14 -19, 2011

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This report was produced for review by the United States Agency for International Development. It was prepared by Marija Joncevska, MD PhD, Quality Project Regional Laboratory Specialist, and Tatiana Bobkova, Quality Project Tajikistan Lab Specialist, for the Quality Health Care Project in the Central Asian Republics.

The USAID Quality Health Care Project is a five-year program designed to improve the health of Central Asians by strengthening health care systems and services, particularly in the areas of HIV/AIDS and TB care and prevention. The project assists governments and communities to more effectively meet the needs of vulnerable populations, with the aim of increasing utilization of health services and improving health outcomes. The Quality Health Care Project is part of USAID's third objective of investing in people as part of the US Strategic Framework for Foreign Assistance.

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ASSESSMENT OF LABORATORY QUALITY MANAGEMENT SYSTEM (QMS) IN THE REPUBLIC OF TAJIKISTAN

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LIST OF ACRONYMS

BSL	Bio-safety level
CD	Cluster of definition (monoclonal antibodies)
CLSI	Clinical and Laboratory Standards Institute
ELISA	Enzyme linked immunosorbent assay
EQA	External quality assessment
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
KfW	German Development Bank (Kreditanstalt für Wiederaufbau)
MOH	Ministry of Health
NRL	National Reference Laboratory
PAP	Papanicolaou screening test for cervical cancer
PCR	Polymerase chain reaction
PHC	Primary health care
QMS	Quality Management System
RCTB	Republican TB Center
SES	Sanitary Epidemiological Services
SNL	Supranational Laboratory
SOP	Standard operating procedures
UNDP	United Nations Development Program
USAID	United States Agency for International Development
WHO	World Health Organization

1. INTRODUCTION

Quality Management System (QMS) can be defined as “coordinated activities to direct and control an organization with regard to quality.” This definition is used by the International Organization for Standardization and by the Clinical and Laboratory Standards Institute (CLSI)¹.

QMS consists of various elements, including all procedures and processes that are performed in the laboratory and must be carried out correctly in order to assure accuracy and reliability of lab services. It also addresses many elements of personnel management and oversight, encouragement, and motivation.

In order to have a functioning QMS, the structure and management of the laboratory must be organized so that quality policies can be established, implemented, and monitored. QMS ensures that:

- The laboratory organization and infrastructure provide appropriate working conditions;
- The right equipment is installed correctly and works properly, and there is a system for maintenance;
- Procedures for selection and purchase are designed to assure that all reagents and supplies are of good quality and that they are used and stored in a manner that preserves integrity and reliability;
- There is an established process of control for laboratory procedures, including sample handling, quality control of testing, and methods for verification and validation; and
- Laboratory data management assures accuracy and confidentiality of test results, as well as accessibility to the laboratory staff and to the health care providers.

The primary goal of QMS is continuous improvement of the laboratory processes, and this must be done in a systematic manner. Laboratory quality standards are an important part of the quality improvement process, serving as benchmarks for the laboratory.

2. BACKGROUND

Tajikistan is a landlocked, predominantly mountainous country that is divided into four main regions: Sogd Oblast in the North; the Region of Republican Subordination (RRS), which includes the capital city, Dushanbe and the Raksht Valley; Khatlon Oblast in the Southwest; and the mountainous Gorno Badakshan Autonomous Oblast in the West. The estimated total population is 7,627,200 (July 2011 estimate). Tajikistan is the poorest country in Central Asian region, and it is estimated that more than 60% of the population lives in abject poverty. The economy depends heavily on cotton, aluminum, electricity exports, and increasingly, remittances from Tajik migrants living in the Russian Federation. According to

¹ Laboratory Quality Management System. WHO/HSE/IHR/LYO/2009.1

the United Nations Development Program's (UNDP) Human Development Index rankings, Tajikistan ranks 112th out of 192 countries.

The breakdown of the Soviet Union and the civil war that ran from 1992 until 1997 damaged the already weak economic structure of the country and seriously affected the existing health care system. The lack of drugs, lack of functioning equipment, and the high turnover of qualified staff resulted in increased morbidity, especially with regards to communicable diseases. The large, hierarchically organized Soviet health system could not survive and provide adequate care. Recognizing this problem, the Government of Tajikistan introduced health sector reform in order to strengthen primary health care (PHC) and rationalize the highly specialized services and large network of diagnostic laboratories. The initiative for rationalization of the public health laboratory network was supported by the World Health Organization (WHO), and the initial assessment mission took place in January 2011. WHO supported the organization of a thematic working group on laboratory capacity strengthening to work with international lab experts to develop a comprehensive model of a public health laboratory network within the 2010-2020 National Health Strategy.

The USAID Quality Health Care Project will provide technical support for practical implementation of the system for laboratory quality management. The Quality Project began its work by conducting an assessment of the current system for laboratory management and will provide technical assistance in the development of QMS guidelines, technical training, implementation, and monitoring.

3. TERMS OF REFERENCE FOR THE ASSESSMENT

The assessment will:

- 1) Identify gaps in QMS concerning the management of the laboratory environment, equipment, supplies, and laboratory and quality assurance methods;
- 2) Identify the priority actions for quality improvement of lab services; and
- 3) Identify national and international partners involved in laboratory QMS implementation and coordinate planned activities.

4. ASSESSMENT METHODOLOGY

Dr. Marija Joncevska, Quality Project Regional Laboratory Specialist; Tatiana Bobkova, Quality Project Lab Specialist; and Dr. Firuza Maksumova, Ministry of Health (MOH) Supervisor of PHC facilities, conducted the assessment on March 14 -19, 2011.

Relevant information concerning the current system for laboratory quality management was collected through:

- 1) Review of policy documents, reports, and other publications concerning the structure and functioning of laboratory service in Tajikistan. The list of documents can be found in Annex 2.

- 2) Site visits: the team visited health facilities with different levels of laboratory services to observe daily routines and talked with laboratory staff. Brief reports on site visits are included later in the report.
- 3) Meetings: the assessment team met with the Deputy Minister of Health, Dr. Sohibanazar Bokievich Rahmonov; the Head of the WHO Country Mission in Tajikistan, Dr. Pavel Ursu; the Head of the Government Agency for Supervision of Medical Services, Dr. Gafur Muhsinovich Hodzamurodov; the Director of the Republican Service for Sanitary Epidemiological Surveillance (SES); and other international and national partners. The full list of persons met can be found in Annex 3.

5. FINDINGS

5.1 ORGANIZATIONAL STRUCTURE AND FUNCTIONING OF LABORATORY SERVICES

The large structure of the laboratory network, which was established according to the Soviet model, was comprehensive but not efficient. MOH is responsible for public health facilities at the national level and for specialized vertical programs. Local health authorities are responsible for oblast- and rayon-level facilities. There are also health facilities for specific ministries and agencies which provide health services just for workers employed by those ministries and their families (e.g. Ministry of Defense, Ministry of Internal Affairs, Ministry of Justice, etc.). The SES laboratory network is responsible for communicable disease surveillance and outbreak response at the national level and has 73 additional stations present in the territory at different administrative levels. Officially, SES laboratories should serve as reference laboratories for bacteriology, virology, and sanitary microbiology, but due to the lack of reagents, those services are not available at all levels. Some diagnostic services are available at microbiology labs at the Institute of Preventive Medicine. The private sector is still not well developed, and private laboratories are functioning only in private hospitals. Although the network of diagnostic laboratories is large, the spectrum of available diagnostic tests is limited to basic clinical and biochemical analyses. For example, the Papanicolaou screening test (PAP) for early diagnosis of cervical cancer is not even available at oblast health centers.

Table 1. Government structure of laboratory services

Organization	Responsibility	Services	Levels
Medtechservice	Technical maintenance and service of lab equipment.	Certification of lab equipment.	National and Oblast
Republican Center for Procurement of Medical Supplies and Medical Equipment	Procurement and distribution of medical supplies and equipment.	Storage of medical reagents and supplies. Ensuring cold chain for special storage requirements. Transport and distribution to periphery.	Central and Oblast
Government Agency for Supervision of Medical Services	Coordination of activities for quality assurance of medical services.	Control of activities related to work with infectious agents. Development and approval of regulatory documents concerning medical services. Accreditation of medical facilities	National

		and laboratories. (Accreditation standards are in development.)	
Gosstandard	Standardization of lab equipment.	Check up and certification of measurement equipment.	National
Sanitary Epidemiological Surveillance (SES)	Development and approval of national standards; practical recommendations; sanitary norms; and requirements for epidemiological safety. Scientific and operational research in prevention of epidemic diseases.	Diagnosis of infectious diseases. Monitoring of infection control in health facilities. Accreditation of bacteriological labs.	National and Oblast
Commercial companies: "Diagnosticum" "Novo Best" "Vital" "Novo Best"	Distributors of laboratory reagents and supplies.	Delivery of reagents and supplies.	National

In order to ensure proper functioning of lab services and to avoid unofficial payment, MOH issued Order #600, introducing the out-of-pocket payment for all diagnostic tests. Free-of-charge services are only available for certain social categories of patients, including World War II participants; retirees who have contributed significantly to the country; individuals affected by the Chernobyl disaster; the disabled; poor and unemployed citizens; and elderly citizens over the age of 80, for the diagnosis of certain medical conditions and diseases, including heart attack, terminal cancer, hemophilia, diabetes, leprosy, TB, and diphtheria.²

Out-of-pocket payment for lab services created a material basis for uninterrupted functioning of lab services, provision of reagents, equipment, and salaries for health workers. Prices for lab tests are variable and are defined by each health facility. Although the prices are higher in private hospitals, patients would rather go to private rather than public hospitals if they can afford to do so. There is not yet an established system for quality assurance of lab services to provide information on the quality of services, and the opinion of the general population is mainly based on the belief that higher cost ensures better quality. However, in such a large and complex network of laboratories it would not be possible to organize a reliable and efficient system for quality assurance.

Table 2. Diagnostic services provided by laboratory network in Tajikistan

Organization	Central level	Oblast level	Rayon/ City	Comments
SES	X	X	X	Bacteriology; Serology; PCR

² Rules of payment and co-payment for medical and sanitary services provided to citizens of the Republic of Tajikistan in state health facilities. Joint order of the Ministry of Health and the Ministry of Finance of the Republic of Tajikistan dated February 10, 2009, #81-11

National TB Program	X	X	X	TB Bacteriology; clinical bio-chemistry
National AIDS program	X	X	X	HIV diagnosis
Centers for Dermatovenereology	X	X	?	Clinical bio-chemistry
Reproductive Health Centers	X	X	X	Clinical bio-chemistry
National Medical Center	X			Clinical bio-chemistry
National Diagnostic Center	X			Clinical bio-chemistry; immunology
Tajikistan National Medical University “Abdula Ibn Sino”	X			Clinical bio-chemistry
Tajik Institute for Postgraduate Training	X		X	Clinical bio-chemistry
Tajikistan Scientific Institute of Gynecology, Obstetrics, and Pediatrics	X			Clinical bio-chemistry
Republican Scientific Center of Pediatrics and Pediatric Surgery	X			Clinical bio-chemistry
National Scientific Center of Prophylactic Medicine	X			Bacteriology; Virology; Immunology
Republican Scientific Center of Cardiovascular Surgery	X			Clinical bio-chemistry
Republican Scientific Blood Center	X	X		Blood safety
Republican Scientific Oncology Center	X	X(1)		Clinical bio-chemistry; histology
Republican Center of Narcology	X	?	X	?
Republican Center of Ophthalmology	X	-	-	?
Republican Center of Cardiology	X	+	-	Clinical bio-chemistry
Republican Clinical Center of Urology	X	-	-	Clinical bio-chemistry
Republican Orthopedic Center	X	-	-	Clinical bio-chemistry
Republican Clinical Center of Endocrinology	X	X	-	Clinical bio-chemistry
Republican Center for Tropical Diseases	X	?		Clinical bio-chemistry
Republican Center for tropical diseases	X			?
Institute of Gastroenterology	X			Clinical bio-chemistry, histology
Children’s hospital			X	Clinical bio-chemistry
Oblast Hospital		X		Clinical bio-chemistry
Oblast Obstetric Clinic		X		Clinical bio-chemistry
Health Center			X	Clinical bio-chemistry
Municipality Hospital			X	Clinical bio-chemistry
Rayon Hospital			X	Clinical bio-chemistry
Private diagnostic labs			X	Clinical bio-chemistry

5.2 LABORATORY QUALITY MANAGEMENT SYSTEM

During the Soviet period, a large number of regulatory documents concerning laboratory quality management were issued by government institutions, including MOH and SES. Some of these documents required standards that were not applicable in routine practice. Some elements of that system, which are still in place, include basic requirements for infection control (provided by SES) and calibration and certification of laboratory equipment provided by Tajik Gosstandart. However, the quality standards, which are currently used, are outdated, and some of them are not in line with internationally accepted standards.

Limited funding for lab services has led to a continuous deterioration of lab infrastructure, and major gaps in QMS are present in laboratory infrastructure and working environments, resulting in difficult and unsafe working conditions. A few well-equipped and properly organized labs could be found in the capital, but the laboratories at the PHC level in the periphery are generally in very poor condition. The situation is significantly better in laboratories that have been refurbished and equipped with all required equipment through support from international donors and programs, including the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). Laboratory equipment in those laboratories is used and maintained properly, the staff is well trained, and there are sufficient amounts of reagents and consumables available, which are mainly provided by donor organizations.

5.3 INFECTION CONTROL AND SAFETY

Infection control and laboratory safety is under the jurisdiction of the SES system. SES regulations define the minimum standards concerning environmental protection, including physical, chemical, and bio-hazards. The new law on sanitary-epidemiological protection was issued in 2008 and is based on the normative basis established during the former Soviet system. Additional regulatory documents on laboratory bio-safety have been developed for laboratories in vertical programs (TB, HIV, and Polymerase Chain Reaction (PCR) virology) to introduce higher standards in line with updated international standards recommended by WHO. Vertical program laboratories have been fully equipped and supported by international donors, and the basic conditions for implementation of required measures are in place. Only the well-organized, specialized labs at the national level can provide separation of patient and sample pathways. In lower-level laboratories, infection control measures are not implemented properly. The situation is especially bad in bacteriology laboratories, where the staff is exposed to pathogenic bacteria belonging to risk group two and three pathogens. The way in which bacteriological labs are organized ensures safety for neither lab staff nor patients and the general population. According to official sanitary requirements, contaminated waste from microbiological labs is classified under Category B, which requires use of disposable waste containers, disinfection before disposal, and autoclaving or burning. However, those procedures are not followed in all laboratories.

Standard operating procedures (SOPs) for dealing with accidents and emergency situations are not available.

5.4 LABORATORY EQUIPMENT AND SUPPLY MANAGEMENT

The majority of laboratories at the PHC level use outdated equipment, which may affect the accuracy of lab test results. A regular checkup of laboratory equipment and calibration is provided annually by Tajik Gosstandardt, the government agency for standardization of equipment. However, daily checkups and recoding is not practiced. The decision to replace outdated equipment and procure new equipment is made by individual health facilities, and they are supposed to use a portion of their funds for equipment. Selection of lab equipment is left to the head doctors at individual laboratories. MOH recognizes the need for improvement of lab equipment management, development of standards, and technical specifications for essential laboratory equipment, as well as the establishment of a standardized procedure for selection, procurement, use, and maintenance.

Equipment documentation and SOPs for use and maintenance of equipment are not standardized. Russian and local language translations of the manufacturer's instructions for equipment usage are not available in many laboratories.

Each laboratory is responsible for procurement of reagents from its own funds and for ensuring that reagents are of good quality and available in sufficient quantities. Logbooks for the recording of received reagents and amounts in stock are obligatory and are present in all medical facilities. However, the knowledge in lab supply management is not sufficient, and all elements of lab supply management are not in place. Quantification of needs is based on rough estimation of quantities, and there is no system for regular monitoring of supplies.

Official regulations dealing with procurement procedures and technical specification of reagents are not available. Less attention is paid to laboratory supplies because they are not considered essential for lab quality. Standard quantity reagents and supplies are available in some TB, HIV, and SES virology laboratories that are supported by international donor organizations.

5.5 LABORATORY PERSONNEL

The most common problem in lab service is high turnover of trained staff. After the breakdown of the Soviet Union, trained specialists left the country looking for better paying jobs in Russia. This process has continued and has resulted in decreasing numbers of experienced and trained laboratory specialists. Due to limited financial resources, it is difficult to provide adequate financial motivation to retain trained staff. Aside from low salaries, poor working conditions and limited opportunities for professional development add to the overall dissatisfaction of lab staff.

5.6 PROCESS QUALITY CONTROL

A quality control system for laboratory services has been introduced in certain vertical laboratory systems, including the TB lab network and HIV lab service. A full set of quality control procedures has been introduced in TB lab service, including peripheral laboratories for sputum smear microscopy, intermediate-level oblast TB labs, and the National Reference Lab (NRL). TB culture laboratories are in the process of developing an external quality assurance (EQA) system for this level of lab service. NRL participates in a proficiency testing system organized by WHO and has successfully completed three rounds of proficiency testing. EQA procedures have also been introduced in the Reference Laboratory for HIV, and it is executed by London Supranational Laboratory (SNL). However, lower-level laboratories in the HIV laboratory network are not included in the EQA system.

Implementation of procedures for internal quality control in clinical laboratories is limited to automated systems, using commercially available kits and standards for quality control and calibration.

Use of SOP documents for pre-examination, examination, and post-examination phases are not available in clinical laboratories. Laboratory procedures are performed based on the knowledge of laboratory staff, instructions recorded in notebooks, or old handbooks and manuals from the Soviet period. Internal quality control is practiced only in higher-level laboratories.

5.7 LABORATORY INFORMATION MANAGEMENT

Management of laboratory information, including written policies, procedures, and laboratory records and reports, varies from laboratory to laboratory depending on the system to which the laboratory belongs. Each laboratory is obliged to maintain a minimum amount of information, including records of all diagnostic tests completed with accompanying test results; and documentation on equipment, equipment passports, and instructions for use of disinfectants. Standardized SOP documents for laboratory procedures are not required. Laboratory test reports are given to patients, and communication and information sharing between laboratory and clinicians is not routine. Samples for lab analysis are usually collected in laboratories, even for more specialized procedures such as cervical swab for bacteriology.

The referral system does not recognize different levels of lab services. Patients are paying for laboratory tests, and it is left to them to decide at which level of lab service they would like to be examined. Duplication and repetition of the same test in different laboratories is also an issue for many patients going through diagnostic procedures.

5.8 LABORATORY ACCREDITATION

The process of laboratory accreditation is still not completely defined. Several institutions are involved in the process, and their roles are not clearly defined. The need for development of accreditation standards is well understood by MOH. Currently, SES is in charge of bio-safety aspects while the National Agency for Supervision of Medical Services is supposed to develop the other standards concerning lab equipment, staffing, and quality of reagents.

A new law on accreditation of laboratories in health care facilities was issued in May 2007 identifying the National Agency for Supervision of Medical Services as the main accreditation body. The agency consists of two departments: a department for supervision of pharmaceutical services and a department for supervision of medical services. As of now, the medical department has not developed accreditation standards, while the pharmaceutical department already has issued some standards concerning the importation of drugs and lab reagents. Standards and minimum technical specifications for lab equipment have not yet been developed.

Accreditation of clinical labs is included in the accreditation procedure for clinics and hospitals, with no specific accreditation requirements. More specific requirements are included in the accreditation procedure for microbiology labs, according to Prikaz #12 from June 2010. Requirements are set by SES and included in the document on sanitary norms and rules (San Pin). However, those standards are not always in place since the accreditation procedure is initiated by individual laboratory request, and the number of laboratories interested in accreditation is very low.

Currently, there are 130 microbiology labs in the country, 68 of which are included in the SES structure.

6. SITE VISITS

6.1 REPUBLICAN HOSPITAL KARABOLO

The republican hospital serves as a third-level health facility, providing diagnosis and treatment of communicable and non-communicable diseases. Health services are available for the entire population of Tajikistan. The laboratory is situated in a separate building, and the condition of the building is very poor. The organization of work does not allow implementation of basic infection control measures. Equipment is outdated and, although regularly checked by Tajik Gosstandardt, does not seem to provide accurate diagnosis. Written instructions are not available at the working place, and laboratory technicians are performing lab procedures as required by the senior laboratory staff. Reagents and consumables are procured by the hospital from their own funds. Consumable supplies and glassware were not available in sufficient quantities.

The head of the laboratory at the hospital is also the Chief Laboratory Specialist at MOH, and he is a member of the MOH monitoring team. The monitoring team is responsible for ensuring the quality of work in health facilities nationwide and conducting visits according to the monitoring plan, which is prepared annually. The evaluation of laboratory work is mainly based on observation of routine work and checks of lab registers. No written instructions, standards, or lab checklists are available. Besides monitoring, lab issues are discussed in meetings with oblast lab specialists, which are held once a month.

Quality control is not practiced regularly, although there are some initiatives to do inter-laboratory re-checking of selected samples. The main purpose of re-checking is to compare results from testing with reagents and equipment provided by different manufacturers.

Decontamination of examined samples is done by using 5% solution of chloramine and washing. Disposable containers for sample collection are not available, nor are containers for disposal of syringes, needles, and broken tubes. Discarded materials are collected and disposed of at a central incinerator.

6.2 POSTGRADUATE TRAINING CENTER FOR FAMILY MEDICINE

The training center was established in Dushanbe at Health Center # 1. The Center started training activities in 2002, and between 2004 and 2009 it was supported through the USAID-funded ZdravPlus project.

The training program includes basic laboratory tests, such as blood tests, blood sugar tests, smear microscopy for sexually transmitted diseases, parasites in stools, and the PAP test. Doctors are supposed to perform these tests at Village Health Posts. However, there is no system in place to ensure that skills gained during the training will be used in the field because basic equipment and reagents are not available at that level of health service.

6.3 REPUBLICAN ONCOLOGY INSTITUTE

The Oncology Institute is situated in a recently refurbished building in the Republican Hospital complex. The laboratory, initially based in the main building, was moved to another building that is old, overcrowded, and in poor general condition. Currently, it serves as the only laboratory providing histopathology examinations for all hospitals in Tajikistan. The laboratory consists of three small rooms in which all procedures, including sample registration, preparation, staining, microscopic analysis, reporting, and slide storage, are

conducted. The methods and equipment used are from the early 1970s. In most cases, patients or relatives bring their biopsy material for analysis and get the material back with the result. It is left to the patients to decide what to do with the tissue samples since there are no defined procedures for medical waste disposal. This is also the only laboratory in the country with the capacity to examine PAP smears.

6.4 NATIONAL DIAGNOSTIC CENTER – DUSHANBE

The National Diagnostic Center serves as a higher-level medical institution, providing all diagnostic services, including laboratory diagnosis, blood analysis, biochemistry, examination of parasites in stools, serology, and immunology. The Reference HIV Lab is situated in the same building, but it is not part of the diagnostic center.

The laboratory is clean, well-organized, and equipped with all essential lab equipment and trained staff. Turnaround time for basic blood and urine analysis is about two hours.

Reagents and consumables are provided from the Center's funds.

Internal quality control is practiced on a weekly basis by re-checking randomly selected samples, without standardized protocols or quality control.

Waste disposal is organized according to official requirements (Prikaz #369): decontamination with 5% chloramine and then it is sent to the central incinerator.

6.5 NATIONAL REFERENCE HIV LABORATORY

National Reference HIV Laboratory belongs to the vertical structure of the National AIDS Program. The laboratory has been fully refurbished and equipped by GFATM grant funds.

The role of the laboratory is diagnosis of HIV, confirmation of HIV-positive results from lower-level labs, and follow-up of AIDS treatment. Using internationally approved and standardized methods, the laboratory performs the following tests: enzyme linked immunosorbent assay (ELISA); Western blot; viral load (real time PCR); and lymphocyte count. All reagents and consumables are available in sufficient amounts. Recommended procedures for safe waste disposal are fully implemented. The laboratory has established a collaborative relationship with an Australian reference laboratory for EQA and receives a panel of samples for testing regularly on an annual basis. The network of HIV laboratories, managed by the reference lab, consists of four oblast and 14 rayon laboratories. At the rayon level, patients are tested with rapid tests and if positive, the diagnosis is confirmed at the oblast level. All oblast-level laboratories are equipped with ELISA systems. Determination of cluster of definition (CD) 4 count is also available at the oblast level.

6.6 NATIONAL REFERENCE TB LABORATORY

The TB laboratory network was supported by several international donor organizations, including USAID, KfW, and WHO, and received GFATM grants from rounds three, six, and eight. Currently the laboratory is based at the Republican Center for TB Prevention (RCTB), functioning as a bio-safety level (BSL) 2 lab. It is equipped with all the necessary equipment and is implementing all internationally recommended methods. However, the laboratory building, although refurbished several times, does not meet all requirements for a TB reference laboratory. A new BSL 3 lab has been organized at the Republican TB Hospital in Machiton, fully refurbished and equipped by a KfW grant. It is not functioning currently, but

the start-up is expected soon after the completion of staff recruiting procedures. Besides financial support, the TB laboratory network received technical support from SNL in Germany, SNL in Italy, and Project HOPE. The staff has been trained in conventional and advanced methods of diagnosis and has successfully completed two rounds of EQA, provided by the German SNL. The TB Reference Lab is also in charge of EQA for the smear microscopy network. Work on the development of SOPs has started with input from Project HOPE (SOP for smear microscopy) and will continue in collaboration with all partners.

The TB laboratory network consists of two BSL 2 culture laboratories in Sogd and Khatlon Oblasts and 96 peripheral laboratories for smear microscopy. Future plans for the reorganization of the laboratory network includes activities for rationalization of smear microscopy network; relocation of the NRL to Machiton hospital; and establishment of a training center for smear microscopy and quality assurance at the RCTB. The development plan is strongly supported by SNL, GFATM, KfW, and Expand TB Project.

6.7 REPUBLICAN SES REFERENCE LABORATORY FOR VIROLOGY

SES laboratories were not assessed during this visit, as they have been the subject of assessment for a recent WHO mission.

The only SES laboratory visited was the Reference Laboratory for Virology, which was completely refurbished and equipped by a WHO project. The laboratory is well-organized and fully equipped as a PCR laboratory. EQA is provided by a reference laboratory in London.

6.8 NATIONAL PROPHYLACTIC CENTER BACTERIOLOGY LAB

The laboratory is attached to MOH and is a higher-level diagnostic and research institution. Currently, the laboratory is in very poor condition, without adequate equipment and functioning in an inappropriate environment in terms of infection control and bio-safety. The laboratory is working with pathogens belonging to risk group two and three, even with multi-drug-resistant strains of *M. tuberculosis*. The government has planned major refurbishment of this facility; however, the start of the work is still uncertain.

6.9 PRIVATE HOSPITAL SHIFO

Established in 2003, Shifo is the first private hospital in Tajikistan. Although the hospital is functioning as a general multi-profile hospital, the capacity of the laboratory is limited to basic clinical and biochemical tests. ELISA is used for diagnosis of sexually transmitted diseases and tumor markers. The hospital, including the laboratory, received accreditation three years ago and is following the same procedures as other government hospitals in terms of implementation of required standards for laboratory equipment and reagents. Quality control is practiced by cross-checking samples with the Republican Hospital, but this is not done on a regular basis.

6.10 VAHDAT RAYON

6.10.1 CENTRAL RAYON HOSPITAL

The Central Rayon Hospital serves 280,000 people from the rayon. Besides this hospital, six other hospitals, 30 village health centers, and 79 medical houses and health facilities belonging to vertical health services (TB, HIV, and SES) provide health services in the region.

Lab services are available at hospitals and some of the village health centers, which can perform basic blood and urine tests.

The level of lab services provided by the Central Rayon Hospital's laboratory does not differ much from other labs in the rayon. In addition to basic blood and urine tests, the laboratory can also perform basic liver functioning tests. The condition of this laboratory is very poor: there is not an adequate water supply, and there is limited capacity for proper waste management. All contaminated waste is burned in a homemade incinerator, placed near the hospital. At the time of visit, the incinerator was not in use, but medical waste, including syringes and bandages, could be seen on the ground nearby.

6.10.2 VAHDAT BACTERIOLOGY LAB

The worst conditions in terms of infection control were found in the Bacteriological Lab in Vahdat Rayon. The required sections for bacteriological labs are nonexistent, equipment is outdated, and diagnostic capacity is very limited. The majority of the samples are examined for pathogenic cocci and enterobacteria. Growth media are prepared in the lab from powder media and were not standard quality. On average, eight to ten samples are examined every day. The most serious problem in this laboratory is the decontamination procedure of grown pathogenic cultures. There is no autoclave in the lab, and decontamination is done with chloramine powder and a water wash. This creates a high risk of infection for laboratory staff as well as for the environment.

7. CONCLUSIONS AND RECOMMENDATIONS

- 1) The existing large network of diagnostic laboratories in Tajikistan cannot efficiently respond to the needs of the national health care system. Levels of diagnostic services are not clearly defined, which often results in duplication of examinations and waste of human and material resources.
 - Recommendation: The rationalization and optimization of the laboratory network should be one of the priority activities within the National Health Strategic Plan (2010-2020). MOH, WHO and other international partners should support the establishment of a thematic working group on laboratory topics with the participation of national and international experts to work on the new structure of laboratory network; the number and distribution of laboratories; and the terms of reference for each diagnostic level.
- 2) Laboratory infrastructure in public health laboratories, especially at the PHC level, is in poor condition. It does not provide an appropriate environment for laboratory staff or

patients. There is no system for transportation of biological samples, and instead of sending samples, patients are sent to laboratories. This further complicates the working conditions.

- Recommendation: The Government of Tajikistan should join forces with international donors to improve laboratory infrastructure and develop a logistics system for transportation of biological samples.

3) Infection control measures in bacteriological labs are insufficient: basic safety equipment such as bio-safety cabinets, safe centrifuges, and autoclaves are not functioning in some laboratories. Required procedures for safe disposal of contaminated waste are not implemented according to international standards.

- Recommendation: Review the current legislation concerning infection control measures in microbiological laboratories and develop national guidelines for infection control based on WHO-recommended standards. Ensure harmonization of standards developed by specialized vertical laboratory services and standards required by Republican SES.

4) The current system for laboratory management cannot ensure the quality of laboratory services according to internationally adopted standards. Regulations which define the minimum standards for the functioning of different types of laboratories should be updated.

- Recommendation: Develop unified quality standards for the organization and functioning of laboratories; technical specifications of lab equipment, reagents and supplies; staff qualification and training needs; and technical procedures and laboratory information systems. International organizations providing technical assistance for these activities should coordinate their activities to ensure that there is no duplication of work.

5) One of the major issues in the functioning of laboratory services in Tajikistan is the lack of a standardized system for internal quality control and EQA. The system has been partly developed in the vertical laboratory structure, but it is still not fully implemented.

- Recommendation: Strengthen the collaboration between vertical laboratory services and public health laboratories. Use lessons learned from the nationwide implementation of the EQA system for quality assurance in the TB laboratory network and develop standardized methods for quality assurance of laboratory examinations. The laboratory working group should initiate the development of standardized protocols and identify the institution which will provide independent EQA for laboratory services.

6) Accreditation standards for laboratories are being developed. Several institutions are involved in the process, but their roles have not been clarified.

- Recommendation: WHO and other international organizations and agencies involved in laboratory strengthening, including UNDP, USAID, and KfW, should support the development of accreditation requirements and work jointly with the Government

Agency for Supervision of Medical Services as an accreditation body. Standards should be developed for all types of laboratory services.

8. ANNEXES

ANNEX 1: AGENDA OF THE ASSESSMENT VISIT

Date	Time	Activity
Friday, March 11	14:00	Arrival Dushanbe
	15:00 – 17:00	Meeting at Quality Project Office
Monday, March 14	9:00 -11:00	Meeting at MOH
	11:00 -13:00	Meeting at Government Agency for Supervision of Medical Services
	13:00 -14:00	Lunch
	14:00 -16:00	Visit to Republican Hospital Karabalo
	16:00 -17:00	Center for postgraduate training in Family Medicine
Tuesday, March 15	9:00 -11:00	National Diagnostic Center
	11:00 -13:00	National Reference HIV Laboratory
	13:00 -14:00	Lunch
	14:00 -17:00	National Reference TB Laboratory
Wednesday, March 16	9:00 -11:00	Republican Oncology Institute
	11:00 -12:00	Republican SES
	12:00 -13:00	National Reference Laboratory for Virology
	13:00 -14:00	Lunch
	14:00 -16:00	National Prophylactic Center Bacteriology Laboratory
Thursday, March 17	9:00 -11:00	Republican Oncology Institute
	11:00 -13:00	Private Hospital Shifo
	13:00 -14:00	Lunch
	14:00 – 17:00	Work at Quality Project Office, summary of findings
Friday, March 18	9:00 – 14:00	Visit to Vahdat Rayon
	14:00 -15: 00	Lunch
	15:00 -16:00	Debriefing at MOH
	16:00 – 17:30	Debriefing at Quality Project Office
Saturday, March 19	14:00 -16:00	Meeting at WHO Country Office

ANNEX 2: LIST OF DOCUMENTS AND REPORTS REVIEWED

Assessment of Bio-Safety Level 3 (BS laboratory at Republican TB Hospital - Machiton, Tajikistan April 29 -30, 2010, M. Joncevska Assessment report, reported to WHO Tajikistan office, M. Joncevska.

Decree on declaring the decree of the Government of the Republic of Tajikistan dated December 2, 2008, #600 "On the procedure of providing medical and sanitary assistance to citizens of the Republic of Tajikistan in state health facilities".

Health Systems in Transition. Vol.12, No. 2 2010. Tajikistan Health System Review, Ghafur Khodjamurodov State Surveillance Center for Medical Activities, Tajikistan Ministry of Health. Bernd Rechel, WHO Country Office Tajikistan.

Национальное руководство по противотуберкулезному инфекционному контролю Республики Таджикистан, Душанбе 2009.

Правила сбора, хранения и удаления отходов лечебно - профилактических учреждений санитарные правила и нормы сАНпИн 2.1.7.020.

Report of the mission to support the Government of Tajikistan in conducting review of public health services. Reported to WHO Tajikistan Office.

Закон об обеспечении санитарно-эпидемиологической безопасности населения (в редакции Закона РТ от 6.10.2008г.№441, от 31.12.2008г.№481).

ANNEX 3: LIST OF PERSONS MET

Abduloeva Mohonim, Head of National Reference TB Hospital

Aliev Samaridin, Director of Republican SES

Bagdasarova Nataliya, Head of pathohistology laboratory, Republican Oncology Center

Bagdasaryan Asya, Laboratory specialist, biochemical laboratory, National Diagnostic Center

Bobohadzaev Oktam, Head of Department for management of medical services

Dzalilova Marofat, Head of laboratory, National Diagnostic Center

Feizuloev Arichon, Head of clinical laboratory, Republican Hospital Karabalo

Hashimova H., Head of Laboratory, National Diagnostic Center

Hodzamuradov Gafur, Head of the Government Agency for supervision of medical services

Hoshimova Sh., Head of laboratory, Private Hospital Shifo

Huseinov Zafar, Director, Republican Oncology Center

Kaisirov Vaisidin, Head of laboratory, Vahdat Rayon Central Hospital

Magzumova Firuza, Head of Department for PHC service

Mahmudova G., Lab specialist, Vahdat Rayon Central Hospital

Murodova G., Lab specialist, National Institute of Prophylactic Medicine

Nazirov Dzamshed, Head of Health Administration, Vahdat Rayon Health Center

Rahimova Tatiana, Lab specialist, AIDS Center

Rahmonov Sohob, Deputy Minister, Ministry of Health of Tajikistan

Saidova Hurshed, Scientist, National Institute of Prophylactic Medicine

Shekhov Abdurahim, Director of Republican TB Hospital

Volkova Tatiana, Head of PCR Virology Laboratory